INTRODUCTORY COMMENTS

In response to the Office Action dated February 14, 2003, please amend the above-identified application as follows:

REMARKS

Claims 1-18 are pending in the application, and claims 1-18 have been are rejected. Claims 1, 5, and 12 have been amended, and 3, 7, and 14 have been cancelled.

I. CLAIM REJECTION UNDER 35 USC § 102

Examiner rejects claims 1, 2, 4, 6, 7, 10, 11, 12, 13, 15, and 18 under 35 U.S.C § 102(b) as being anticipated by USP 6,048,350 to Vrba.

Examiner states that regarding claims 1, 6, 7, 10, 11, Vrba discloses a catheter comprising an elongate shaft (shaft 12) and a balloon having a flexible wall (balloon 16, an intermediate body (16B), proximal and distal cones (16A and 16C), proximal ends, and at least one circumferential groove formed of the balloon wall adjacent a transition between the intermediate body and a cone (FIG. 2 spaces 22), and a balloon expandable stent (stent 20). Applicants respectfully disagree. Vrba does not disclose a circumferential groove formed in the balloon as shown in Applicant's FIGs 2-5. Vrba discloses in column 3, lines 29-37 a balloon catheter 10 having stent mounting bodies 24. Stent mounting bodies 24 of Vrba are disks that extend radially away from the central catheter shaft and beyond the diameter of a deflated balloon. Stent mounting bodies 24 are used to retain stent 20 and prevent stent 20 from contacting balloon catheter 10 (they are standoffs). In fact, Vrba discloses that stent 20 is fastened to stent mounting bodies 24 through various means such as locking ridges or adhesives (FIG. 3, column 3, lines 53-62).

More to the point, spaces 22 are disclosed exactly one time in the detailed description of Vrba. It is disclosed on column 3, lines 48-50 in describing FIG. 2. FIG. 2 of Vrba is a picture of balloon catheter 10 fully inflated such that stent 20 is expanded to its final state. Applicant's respectfully submit that spaces 22 only refer to the area of balloon catheter 10 having stent mounting bodies 24. In fact, column 3, lines 48-50 states that when inflated, balloon elements may completely surround and overlap the spaces 24. Referring to FIG. 2 of Vrba, the spaces 22 correspond to the region where stent mounting bodies 24 reside. In FIG. 2 the spaces 22 are not covered when the balloon catheter 10 is inflated. Thus, it is believed that the description quoted hereinabove is meant to describe the situation when balloon catheter 10 is inflated each balloon element will expand radially outward but could also expand longitudinally thereby covering spaces 22 and stent mounting bodies 24. Nowhere in Vrba is there mention of forming a groove in balloon catheter 10 nor the special manufacturing steps that would have to be taken to make such a groove as disclosed in Applicant's disclosure. Therefore, it is respectfully submitted that Applicant's claims 1, 6, 7, 10, and 11 distinguish over the cited reference and are therefore believed allowable. Dependent claims 2-5, 7-9, and 11-14 are believed to properly depend respectively from Applicant's independent claims 1, 6, and 10 and are believed allowable therewith.

Examiner states that regarding claim 2, Vrba discloses that the circumferential groove has a shape selected from C-shapes, U-shapes, W-shapes, and open-sided polygons (FIG. 2 spaces 22). Applicant's respectfully submit that there is no mention of a groove being formed in balloon catheter 10 of Vrba nor is there mention of shaped grooves. Spaces 22 only refer to the area of balloon catheter 10 where the stent mounting bodies 24 are placed.

Examiner states that regarding claims 4, 12, 13, and 18, Vrba discloses that the at least one circumferential groove is at least partially filled with a flexible material that is adhered to the balloon (Column 3, lines 53-62). Applicant's respectfully disagree. Column 3, lines 53-62 describe how stent 20 connects to and is held by stent mounting bodies 24. In particular, it states that receiving portion 26 of the stent mounting bodies 24 mate with stent 20 and then goes on to describe various methods for doing this such as locking ridges or adhesives. Thus, this description has nothing to do with a groove nor filling such a groove.

Examiner states that regarding claim 15, Vrba discloses a method comprising the steps of providing a catheter having an elongate shaft (shaft 12), mounting a balloon around a distal end of the shaft, collapsing the balloon around the catheter shaft (FIG. 1 and column 3, lines 24-36), and mounting a balloon expandable stent in a radially compressed configuration around the intermediate body of the balloon (column 3, lines 29-36). Applicant's respectfully disagree. Vrba does not teach "mounting a balloon expandable stent in a radially compressed configuration around the intermediate body of the balloon. In general, Vrba actually teaches away from radially compressing the balloon expandable stent around the intermediate body of the balloon as claimed by Applicant. Vrba does not want the stent compressed to the balloon body. The reason for Vrba's stent mounting bodies is to prevent the stent from being placed on a deflated balloon catheter by allowing the stent to be attached to the stent mounting bodies instead of the balloon. Another fact that is substantially different is that Vrba teaches placing the stent extending past the intermediate body as defined by the location of the stent mounting bodies (see FIGs 1 and 2 of Vrba). Applicant's claim placing the stent around the intermediate body of the balloon. Also, Vrba does not have a circumferential groove formed of the balloon wall adjacent a transition between the intermediate body and the proximal and distal cones as claimed by Applicant's and discussed in detail hereinabove. Therefore, it is respectfully

submitted that Applicant's claim 15 distinguishes over the cited reference and is therefore believed allowable. Dependent claims 16-18 are believed to properly depend respectively from Applicant's independent claim 1 and are believed allowable therewith.

Examiner states regarding claims 1-3 that they are rejected under 35 USC 102(b) as being anticipated by USP 5,545,132 to Fagan et al. Examiner states regarding claims 1-3 that Fagan et al. discloses a balloon having a flexible wall, an intermediate body (balloon 12), proximal and distal cones (cones 18 and 20), proximal and distal ends, and at least one circumferential groove formed of the balloon wall adjacent a transition between the intermediate body and a cone (groove 16), the groove having a shape selected from C-shapes, U-shapes, W-shapes, and open-sided polygons (FIG. 1 groove 16), and wherein the diameters measured distal and proximal to the at least one circumferential groove are uneven (FIG. 3 end near cone 20).

Applicant's respectfully disagree. Fagan et al does not teach at least one circumferential groove formed of the balloon wall adjacent a transition between the intermediate body and a cone as claimed by Applicants. In column 3, lines 32-35, Fagan et al describes the FIG. 1 reference used by Examiner in the rejection hereinabove. Fagan et al discloses a helical groove 16 that extends the length of the balloon preferably from a cone 18 to a cone 20. Applicant's claim at least one circumferential groove formed of the balloon wall adjacent a transition between the intermediate body and a cone. The helical groove of Fagan traverses the entire length of the balloon from proximal cone to intermediate body to distal cone. Applicant's claimed groove is in the transition between a cone and intermediate body. The groove as disclosed by Applicants goes around the entire circumference of the balloon at this transition point between cone and intermediate body. One benefit of placing the groove at the transition point between cone and intermediate body is to retain the stent on the intermediate portion of the body during delivering the stent. The helical groove described in Fagan et al would not

provide this benefit because it extends from across the entire balloon structure. The helical groove of Fagan et al is for increased flexibility and to allow the perfusion of blood past the dilation catheter (in essence a channel) as disclosed in the description. Therefore, it is respectfully submitted that Applicant's claim 1 distinguishes over the cited reference and is therefore believed allowable. Dependent claims 1-5 are believed to properly depend respectively from Applicant's independent claim 1 and are believed allowable therewith.

II. CLAIM REJECTION UNDER 35 USC § 103

Claims 8, 9, 14, 16, and 17 are rejected under 35 USC 103(a) as being unpatentable over Vrba '350 in view of USP 5,935,135 to Bramfitt et al. Examiner states that Vrba discloses the claimed invention except for the cones having a larger deflated diameter than the deflated intermediate portion of the balloon. Bramfitt teaches that the enlarged cone sections are provided to restrain movement of the stent without changing the overall profile of the delivery system, preventing damage of the balloon by the stent, eliminating the biocompatibility problems of adhesives and the retractibility of protective sheaths. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the stent delivery system of Vrba with enlarged cone sections of Bramfitt in order to restrain the movement of the stent during delivery without changing the delivery system's overall profile, preventing damage to the balloon by the stent, eliminating biocompatibility problems associated with adhesives, and eliminating problems associated with the retractibility of a protective sheath.

Applicant's respectfully disagree, claims 8-9, 14, 16-17 are dependent claims respectively to claims 6, 10, and 15. Examiner is well aware of the three basic criteria necessary to establish a prima facie case of obviousness. First, there must be some suggestion or motivation, either in

the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success, and third, the prior art reference or references must teach or suggest all of the claim limitations. The teaching or suggestion to make the combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicants' disclosure. In Re Vaeck, 947 Fed. 2d 488, 20 USPQ 2d, 1438.

Applicant's reiterate that Vrba does not teach a circumferential groove formed of the balloon wall adjacent a transition between the intermediate body and one of the proximal and distal cones which is discussed in greater detail hereinabove. Similarly, Bramfitt does not teach a circumferential groove. Thus, neither of the prior art references teach or suggest all of the claim limitations.

Also, there is no suggestion or motivation to one skilled in the art to combine the reference teachings. Vrba teaches the addition of stent mounting bodies to the balloon body. The stent mounting bodies are disks that extend radially beyond the deflated balloon body. The stent mounting bodies are designed to hold the stent in a place during delivery and prevent intimate contact of the stent to the balloon body. Bramfitt teaches the opposite. The stent in Bramfitt has intimate contact with the balloon body. Movement of a stent in Bramfitt is prevented by the addition of cuffs formed on the balloon body that act as stop. Thus, there would be no motivation to combine Bramfitt to Vrba since they both provide different solutions where one relies on stent to balloon contact and the other does not. Therefore, it is believed that independent claims 1, 6, 10, and 15 are unobvious in view of the Vrba and Bramfitt references taken singly or in combination. Dependent claims 8, 9, 14, 16, and 17 are believed to properly depend, either directly or indirectly from their corresponding independent claim and are believed allowable therewith.

Claim 5 is rejected under 35 USC 103(a) as being unpatentable over Vrba '350 in view of USP 6,254,608 to Solar. Examiner states that Vrba discloses the claimed invention except for the flexible material comprising a foamed material. Solar teaches that a foamed material is used for bonding the stent to the catheter to allow the stent to become embedded in the balloon in order to protect the anatomical passageways during delivery of the stent and prevent the stent from slipping without the use of a protective sheath.

Once again, Vrba does not teach a circumferential groove formed of the balloon wall adjacent a transition between the intermediate body and a cone as recited in independent claim 1. Similarly, Solar does not teach a circumferential groove. Thus, neither of the prior art references teach or suggest all of the claim limitations.

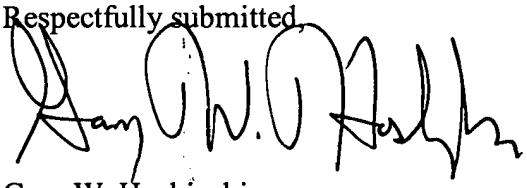
Also, there is no suggestion or motivation to one skilled in the art to combine the reference teachings. Vrba teaches the addition of stent mounting bodies to keep the stent away from the balloon body. Solar teaches the opposite. The stent in Solar is made an integral part of the balloon body. Thus, there would be no motivation for one skilled in the art to combine the teachings since they teach away from one another. Therefore, it is believed that independent claim 1 is unobvious in view of the Vrba and Solar references taken singly or in combination. Dependent claim 5 is believed to properly depend, either directly or indirectly from claim 1 and is believed allowable therewith.

III. CONCLUSION

In view of Applicant's amendments and remarks, it is respectfully submitted that Examiner's rejections under 35 USC § 103, have been overcome. Accordingly, Applicants respectfully submit that the application is in condition for allowance, and such allowance is therefore earnestly requested. Should the Examiner have any questions or wish to further discuss this application, Applicants request that the Examiner contact the undersigned at (480) 385-5060.

If for some reason Applicants have not requested a sufficient extension and/or have not paid a sufficient fee for this response and/or for the extension necessary to prevent abandonment on this application, please consider this as a request for an extension for the required time period and/or authorization to charge deposit Account No. 50-2091 for any fee which may be due.

Respectfully submitted,



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Dated: June 24, 2003

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